

REMARKS/ARGUMENTS

Please reconsider this application in view of the above amendments and the following remarks. Claims 1-22, 24, 25, and 27-39 are pending. Claims 1-22, 24, 25 and 27-39 are rejected. Claims 1, 10, 21, and 31 are amended.

Applicant thanks the Examiner for the telephonic interview on May 23, 2007 where the technology utilized in the present invention and in the prior art was discussed.

Amendments to the Claims

Claims 1, 10, 21, and 31 have been amended. Claims 1, 10, 21, and 31 have been amended to remove the element directed to a smoother coating surface. Applicant considers this to be a broadening of the claim. Also, claim 1 now recites that the pressure is always below the critical pressure. This amendment is supported by the specification in paragraph [0018].

Claims 10 has been amended with respect to the term “the coating” to resolve any potential antecedent basis issues.

First Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected Claims 1-9 under 35 U.S.C. section 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses the rejection in view of the amendment to claim 1.

Claim 1 has been amended to recite that the pressure and temperature in the chamber are always below the critical pressure and temperature. Claim 1 is fully supported by the specification as-filed. The specification discloses at paragraph 5 coating of a stent by applying a composition including a polymer dissolved in a solvent and a therapeutic substance dissolved or dispersed in the solvent. Paragraph 5 also discloses the “solvent is allowed to evaporate to form the coating.” The specification further teaches at paragraph 18 that “increasing the pressure ... above ambient pressure causes the solvent to evaporate more slowly leading to a coating with a smoother surface.” Forming a coating through evaporation of a solvent requires the coating conditions to be below the critical point of the solvent since a substance at super critical

conditions does not exhibit a liquid-gas phase transition, and thus, does not evaporate. At no point does the pressure go above the critical pressure. Please remove the rejection of claims 1-9.

Second Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected Claims 10-20 under 35 U.S.C. section 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses the rejection for at least the following reasons.

The Examiner indicates that the following language in claim 10 regarding “wherein the coating is formed on the device through evaporation of the solvent . . .” is new matter that was not in the specification as-filed. The Examiner is directed to paragraph [0008] of the application as-filed where “a method of forming a coating for a stent” includes “adjusting the pressure of the chamber to increase or decrease the evaporation rate of the fluid.” Additional support is found in paragraphs [0017] and [0018]. Applicant respectfully asserts that the language in claim 10 is fully supported by the specification as-filed and requests reconsideration and withdrawal of the rejection of claims 10-20.

Third Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected Claims 4, 13, 25 and 34 under 35 U.S.C. section 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses the rejection for at least the following reasons.

The rejected claims state that the solvent comprises a compound selected from the list. Even though dimethylsulfoxide is listed on Table 1 of the specification as being a “non-volatile” solvent, if it is combined with a volatile solvent, the resulting solution may also be a volatile solvent. Thus, Applicant respectfully asserts that the language in claims 4, 13, 25 and 34 fully comply with the written description requirement and requests reconsideration and withdrawal of the rejection of these claims.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 1-22, 24-25 and 27-39 under 35 U.S.C. section 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly

claim the subject matter which applicant regards as the invention. Applicant respectfully traverses the rejection. Amendments to claims 1, 10, 21 and 31 removing the “smoother” language should obviate rejections of these claims. With respect to claim 1 and “the coating” language, Applicant submits that the language is clear because of the mention of the coating process in the preamble. The amendment to claim 10 of “the coating” to “a coating” obviates the rejection of claim 10. With respect to claims 3, 12, 21 and 31, an antibiotic may be combined with any of the other types of the drugs listed, including combinations of these drugs. Applicant asserts that the language is clear. With respect to claims 4, 13, 25 and 34, Applicant asserts that the language used in the claims is acceptable Markush language. Although the M.P.E.P. in section 2173.05(h) makes suggestions as to Markush language, such as the words suggested by the Examiner, the language is not a requirement as long as there is no uncertainty or ambiguity in the scope or clarity of the claims. Reconsideration and withdrawal of the rejections are respectfully requested.

Rejections under 35 U.S.C. § 102

The Examiner has rejected Claims 10-39 under 35 U.S.C. section 102(e) as allegedly being anticipated by Mehta et al. (US 2002/0051845). Applicant respectfully traverses for at least the following reasons.

Page 6 of the Office action states that “it is the examiner’s position that the solvent [of Mehta] at some point in time does evaporate from the coating.” This is not physically possible in view of the physics involved during phase transitions. Applicant has attached a phase diagram showing the different transitions between the different states. As described in more detail below, applicant’s claims are directed to an evaporation (vaporization on the diagram) operation, whereas Mehta et al. disclose a deposition or precipitation type of operation at supercritical conditions. A supercritical fluid cannot evaporate, i.e., cross the liquid-gas equilibrium line, as shown on the phase diagram. More specific arguments for groups of the claims are made below.

Also on page 6, it states that “it is the examiner’s position that one skilled in the art would recognize that spraying is an equivalent and alternative process to the Mehta deposition process.” It is further noted that the Examiner has only made an anticipation rejection under 35 USC § 102. Anticipation may only be shown if each and every element as set forth in the claim

is found in a single reference. Even if the Examiner's statement were correct, the Examiner is proposing a modification of the prior art and the Examiner's statement looks curiously similar to the language used in an obvious type rejection. Equivalent or alternative processes are not included as a basis for rejection in the patent laws under § 102. Thus, Applicant requests reconsideration and removal of the rejections based on equivalent or alternative processes.

Claims 10-20

Claim 10 recites "applying a composition comprising a solvent to the implantable device while the device is disposed in an environment having the pressure at greater than ambient pressure, wherein a coating is formed on the device through evaporation of the solvent."

Mehta et al. teach contacting a "stent or other medical device with a liquid coating solution comprising a film forming biocompatible polymer and an optional therapeutic agent in a solvent under super critical temperature and pressure, such that the polymer and therapeutic agent are solubilized under the super critical conditions but insoluble under sub-critical conditions." (Mehta et al., paragraph 8) Mehta et al. then teach "reducing the pressure and/or temperature conditions to sub-critical levels to deposit a thin film coating of said polymer and optional therapeutic agent on the stent or other medical device." (Mehta et al., paragraph 9) The coating is deposited since the coating material becomes insoluble in the solvent at sub-critical conditions.

Mehta et al., therefore, teach forming a coating through precipitation or deposition of coating material from a solvent onto a stent, not through evaporation of the solvent. Furthermore, adjusting temperature and pressure of the solvent to supercritical conditions, as disclosed in Mehta et al., does not allow formation of a coating through evaporation since a substance at super critical conditions does not exhibit a liquid-gas phase transition, and thus, does not evaporate. Therefore, claim 10 is allowable since Mehta et al. do not teach the limitation "the coating is formed on the device through evaporation of the solvent." Claims 11-16 and 20 depend from claim 10 and are allowable for at least the same reason that claim 10 is allowable. Reconsideration and withdrawal of the rejection of claims 10-16 and 20 are requested.

Furthermore, as discussed below in reference to claim 21, claims 14-16 are independently patentable.

Claims 17-19 depend from claim 1. Claim 1 is allowable over the cited prior art. Thus, claims 17-19 are allowable for at least the same reason that claim 1 is allowable. Applicant requests reconsideration and withdrawal of the rejection of claims 17-19.

Claims 21-30

Claim 21 recites “the act of applying comprises spraying the composition on the implantable device.” As indicated above, Mehta et al., teach forming a coating by contacting a device with a solvent including coating material at super critical conditions of the solvent followed by deposition of coating material from the solvent onto the device. Nowhere in Mehta et al.’s discussion of this method of coating do Mehta et al. discuss the use of spraying a composition onto a device, e.g., paragraphs 8-9, 50-55, and examples, paragraphs 56-72.

The Examiner states that “the deposition of the coating on the stent or other medical devices is equivalent to a spraying application (paragraph 13, 25, 51).” However, Mehta et al. teach exactly the opposite, i.e., the deposition method of Mehta et al. is not equivalent to spraying. Mehta et al. discuss spray coating of stents in the Background at paragraphs 4 and 5. However, Mehta et al. clearly teach against the use of spray coating in these paragraphs by pointing out the disadvantages of spray coating, for example, “spray coating can be problematic in that there is a significant amount of spray lost during the process and many of the pharmaceutical agents that one would like to incorporate in the device are quite costly.” (paragraph 4 of Mehta et al.)

The coating method disclosed, for example, in the cited paragraphs above is clearly meant as an alternative and an improvement to spray coating. This is made even more evident from Mehta et al.’s statement in paragraph 4 “there is a continuing need for new and improved stent coating techniques.” Furthermore, there is no teaching in Mehta et al. of the use of spray coating a stent in combination with the methods discussed in the cited paragraphs which describes conditions above ambient pressure.

Thus, the combination of the two limitations of claim 21 (1)“applying a composition comprising a solvent and ... while the device is disposed in an environment having the pressure at greater than ambient pressure” and (2)“the act of applying comprises spraying the composition on the implantable device” are not taught by Mehta et al. Even if spraying were equivalent to deposition, claim 21 is not anticipated by Mehta et al. since the a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP Section 2131. Additionally, “the identical invention must be shown in as complete detail as is contained in the ... claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and MPEP Section 2131. Not only is “equivalent” not the same as “identical,” the combination set forth above is simply not “found, either expressly or inherently” in Mehta et al., which is required for there to be anticipation.

Even if “deposition” were equivalent to “spraying,” applicant is unaware of any statutory or case law which supports the Examiner’s position that anticipation can be based on prior art disclosure of “equivalent” features or elements, outside of the context of means- or step-plus-function claim elements. Claim 21 does not contain means- or step-plus-function elements. Should the Examiner maintain the rejection of claim 21, applicant respectfully requests the Examiner cite such authority supporting the rejection.

Thus, claim 21 is allowable. Claims 22, 24, 25, and 27-30 depend from claim 21 and are allowable for at least the same reason that claim 21 is allowable. Applicant requests reconsideration and withdrawal of the rejections of claims 21, 22, 24, 25, and 27-30.

In addition, for the reasons discussed above with respect to claim 21, claims 27 and 28 are independently patentable.

Claims 23 and 26 are canceled.

Claims 31-39

Claim 31 recites “the pressure is selected based on the vapor pressure of the solvent.” In Mehta et al., the pressure and temperature are adjusted based on the critical point of the solvent since the coating material is soluble above and insoluble below the critical point. In addition, at supercritical conditions, a substance does not even have a vapor pressure. Thus, Mehta et al. do

not teach the above-mentioned feature of claim 31. The Examiner is arguing on page 6 of the office action that the various solvents "are selected for the properties. . ." However, claim 31 contains the element of selecting the pressure of the chamber based on the vapor pressure of the solvent. Claims 32-39 depend from claim 31 and are allowable for at least the same reasons that claim 31 is allowable. Applicant requests reconsideration and withdrawal of the rejections of claims 31-39.

Furthermore, as discussed above in reference to claim 21, claims 35-37 are independently patentable.

Since all claims are allowable, please issue a Notice of Allowability directed at these claims.

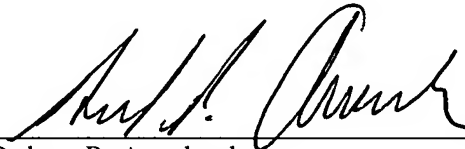
If I can be of any help, please contact me at the number below.

Respectfully submitted,

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6/8/07

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